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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,845	09/24/1999	MARIN JANUSZ	AAT-11612	1703

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EXAMINER	
TELLER, ROY R	
ART UNIT	PAPER NUMBER
1654	26

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/269,845	JANUSZ ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16,24,26-32,35,40,41 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16,24,26-32,35,40,41 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/3/03 has been entered.

In paper NO: 25, received 1/3/03, applicant canceled claims 3-7, 13-14, 17, 33-34, 36, 46-47, 53, and 55-57. Applicant amended claims 15-16, 24, 26-32, 35, 40-41, and 54. Claims 15-16, 24, 26-32, 35, 40-41, and 54 are pending and will be examined in this office action.

The rejection of claims 15, 16, 24, 26-32, 35, 40-41, and 54 under 35 USC 112, first paragraph is withdrawn due to applicant's amendment thereof.

Claim Rejections - 35 USC § 103

The rejection of claims 15, 16, 24, 26, 28-32, 35, 40-41, and 54 under 35 USC 103 are withdrawn. Applicant's arguments were persuasive.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 15, 16, 24, 26-32, and 35 is maintained for the reasons of record and for the additional reasons outlined *infra.*

Claims 15, 16, 24, 26-32, and 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for colostrinin usage as a modest cytokine inducer in human leukocytes does not reasonably provide enablement for treatment of dementia, neurodegenerative diseases or Alzheimer's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard , the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1998) as to undue experimentation.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention:

Colostrinin is used as a medicament and treatment for dementia, neurodegenerative diseases, and Alzheimer's disease.

The state of the prior art and the predictability or lack thereof in the art:

In Inglot (Archivum Immunologiae et Therapiae experimentalis, 1996, vol. 44, pp. 215-224) cited in paper NO: 7, colostrinine is referred to as a modest cytokine inducer in human leukocytes, see title and abstract. In Janusz (Archivum Immunologiae et Therapiae experimentalis, 1993, vol. 41, pp. 275-279) cited in paper NO: 19, ovine colostrum is an immunomodulatory peptide. Treatment for dementia, neurodegenerative diseases and Alzheimer's disease were not investigated. The prior art cited above does not teach of a treatment for dementia, neurodegenerative diseases and Alzheimer's disease, therefore, undue experimentation would be necessary to determine a treatment for dementia, neurodegenerative diseases and Alzheimer's disease involving colostrinin.

The specification has shown an immunomodulation effect occurred when colostrinin was administered to mice and humans. The specification did not show and effect and/or treatment for dementia, neurodegenerative diseases and Alzheimer's disease. The art is still unpredictable in light of Kruzel's (Journal of Molecular Neuroscience, 2001, vol. 17, pp. 379-389)cited in paper NO: 19, abstract which stated"...it is hoped that the beneficial use of colostrinin in Alzheimer's disease...will revive interest in its clinical application for treatment and/or prophylaxis of many age-related disorders."

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991).

The specification showed some guidance with regards to an immunomodulation effect when colostrinin was administered to mice and humans. The specification gave little guidance or direction in the treatment of dementia, neurodegenerative diseases and Alzheimer's disease. In

example IX, pages 19-20 of the instant specification, a method of treatment for early and moderate stages of Alzheimer's disease was investigated. It was found that colostrinin treatment induced a state of hyporeactivity or tolerance.In example X, page 21 of the instant specification, a method of treatment for early and moderate stages of Alzheimer's disease was investigated. It was found that colostrinin treatment induced a state of hyporeactivity or tolerance. Beyond this, no treatment of dementia, neurodegenerative diseases or Alzheimer's disease occurred.

The instant specification gave examples of inducted cytokines with colostrinin *in vitro* on blood taken from healthy and sick volunteers. Patients with early stages of Alzheimer's disease were given Colostrinin/NP tablets in which improved contact and uplift of mood was observed. Alzheimer's disease can only be diagnosed post-mortem with the dissection of the brain. The examples IX and X, pages 19-21 of the instant specification, are not adequate working examples for the treatment of dementia, neurodegenerative diseases or Alzheimer's disease.

The breadth of the claims and the quantity of experimentation needed:

Neurodegenerative diseases are not limited to treatment or condition, examples of neurodegenerative diseases are multiple sclerosis, amyotrophic lateral sclerosis, Parkinson's disease, and sensory recognition problems: sight, feel, paralysis.

Undue experimentation would be necessary in order to determine a treatment for dementia, neurodegenerative diseases or Alzheimer's disease involving colostrinin.

In consideration of each of the above factors, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosures, examples, teachings and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 15, 16, 24, 26, 27, 31, 32, 35, 40, 41, and 54 are rejected under 35 U.S.C. 102(a) as being anticipated by Inglot (Archivum Immunologiae et Therapiae experimentalis, 1996, vol. 44, pp. 215-224) cited in paper No:7.

The claimed invention is drawn to a composition comprising colostrinin in isolated form for use in the treatment of dementia, neurodegenerative diseases and Alzheimer's disease in humans. A dietary supplement for humans comprising colostrinin is recited. A pharmaceutical composition comprising a nonapeptide in isolated form is recited.

Inglot teaches colostrine, a proline-rich polypeptide (PRP), see abstract. Inglot disclose a chemically synthesized PRP, see abstract. Inglot discloses 100 and 200 ug tablets PRP, see abstract. Inglot teaches compositions and methods of making the compound, see page 216, "materials and methods". Inglot discloses using the compound in Alzheimer's patients, see table

2 and 4, page 218 and 219, "results". Inglot teaches use of the compound for humans in the treatment of progressive neurodegenerative diseases, page 223. Inglot discloses the active nonapeptide fragment of PRP, page 216, "materials and methods. Inglot teaches sheep colostrom is commonly used in nutrition, page 222.

The instant specification recites that colostrinin used may be ovine colostrinin or non-ovine colostrinin, page 5, lines 3-4. The instant specification working examples I-X were conducted using ovine colostrinin, example I, page 10, line 21.Absent evidence to the contrary, the colostrinin used in the instant specification encompasses both ovine and non-ovine colostrinin.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT
1654
2/5/03
RT

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